Product Data Sheet

TruQ[™] TMA 2-Core



PRODUCT NAME:	TruQ™ TMA 2-Core				
PRODUCT CODES:	SAM-CS-3DRSTMA-1 CS-3DRSTMA-1/5 CS-3DRSTMA-1/25	Positively Charged Slides 2 Pack Positively Charged Slides 5 Pack Positively Charged Slides 25 Pack			
INTENDED USE:	Research Use Only (validation purposes)				

This product is designed to confer confidence in results obtained from the sample on the same slide. The 3D Reference Standard Tissue Microarray slides and blocks are to be used to monitor the performance of the IHC staining assay during initial validation and for troubleshooting activities. Fixation and processing parameters may differ from the test cases and, as such provide control for all reagents and method steps except fixation and tissue processing. The clinical interpretation of any positive staining or its absence must be evaluated within the context of clinical history, morphology and other histopathological criteria. This material cannot be used independently as a means of optimizing assays in the laboratory.

<u>QUANTITY:</u>	SAM-CS-3DRSTMA-1 CS-3DRSTMA-1/5 CS-3DRSTMA-1/25	Two (2) positively charged tissue slides in slide mailer Five (5) positively charged tissue slides in slide mailer Twenty Five (25) positively charged tissue slides in slide mailer				
STORAGE:	4°C to 25°C. Avoid freezing as this may cause the wax to crack. Avoid temperature above 100° F as the paraffin blocks may start to melt.					
DESCRIPTION:	3D-RS TMA which includes 2 x cores (Diameter 1.5mm) containing two distinct tissues manufactured using a StatLab patented technology of histosynthesis. A reference standard control designed for breast and cervical cancer markers. The tissues are formalin fixed and paraffin embedded following CAP guidelines.					
Fixative: Embedding:	10% Neutral Buffered In paraffin wax	Formalin				



DIRECTIONS FOR USE:

TMA tissue control) slides should be dried at 37°C overnight with 1-2 hrs incubation at 60°C. (see below for guidance on appearance of cores)



Note: It is the responsibility of the end user to determine suitability with their reagents and procedures within their laboratory.

ORIENTATION:

Each control is marked with a puncture mark adjacent below the left core A (present before dewax). The left Core A is 3D reference standard (RS) Breast tissue and the right Core B is 3D reference standard (RS) Cervical tissue.





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EXPRESSION PROFILE:

Antibody	Clone	Core A - 3DRS Breast Tissue		Core B - 3DRS Cervical Tissue	
		Tumor	Stroma	Tumor	Stroma
Pan CK	AE1/AE3	Positive	Negative	Positive	Negative
AE1 (Acidic Type 1-CK)	AE1	Positive	Negative	Positive	Negative
CAM 5.2	CAM 5.2	Positive	Negative	Positive	Negative
CD 44	156-3C11	Positive	Negative	Positive	Negative
СК 5	XM26	Negative	Negative	Positive	Negative
СК 5/6	D5/16B4	Negative	Negative	Positive	Negative
СК 7	OVTL12/30	Positive	Negative	Negative	Negative
CK 8 (LMW-CK)	35βH11	Positive	Negative	Positive	Negative
CK 8/18 (LMW-CK)	DC-10	Positive	Negative	Positive	Negative
c-Myc	EP121	Positive	Negative	Positive	Negative
Collagen IV	Col94	Negative	Positive	Negative	Positive
Epithelial Membrane	Ber-EP4	Positive	Negative	Negative	Negative
GATA-3	L50-823	Positive	Negative	Negative	Negative
HER-2 (CB11)	CB11	2+	Negative	Negative	Negative
Ki.67	SP6	Positive	Negative	Positive	Negative
OSCAR	OSCAR	Positive	Negative	Positive	Negative
P53	DO7	Positive	Negative	Positive	Negative
Topoisomerase II a	31	Positive	Negative	Positive	Negative
Vimentin	SP20	Negative	Positive	Positive	Positive
β-catenin	14	Positive	Negative	Positive	Negative

For more information, contact <u>ihctech@statlab.com</u> or visit our website <u>statlab.com</u>



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